K121280

FEB 8 2013

510(k) Summary

10.1 Submitter:

Hologic, Inc
250 Campus Drive
Marlborough, MA 01752 USA

Contact: Sarah Fairfield
GYN-Surgical Division
250 Campus Drive
Marlborough, MA 01752 USA
508-263-8857

Date prepared: January 16, 2013

10.2 Device Information:
Trade Name: MyoSure Instrument Tray
Common Name: Sterilization Tray
Classification II (21 CFR 880.6850)
Product Code: KCT

10.3 Predicate Device:
Trade Name: PolyVac Surgical Instrument Delivery System
Submitter/510(k) holder: Symmetry Medical, Inc.
510(k) Numbers: K012105 and K040223

10.4 Device Description
The MyoSure Instrument Tray consists of an approximate 13.45 inch x 8.41 inch x 2.0 inch plastic, perforated base and lid with posts and cradles to position the devices to be sterilized. Each tray and lid has an evenly distributed hole pattern that allows sterilant penetration and air removal.

10.5 Indications for Use
The MyoSure™ Instrument Tray is intended to enclose, protect, and organize the MyoSure Rod Lens Hysteroscope, MyoSure Removable Outflow Channel, and associated components during sterilization and storage. The MyoSure Instrument Tray must be used in conjunction with a sterilization wrap that is cleared by FDA for the indicated sterilization cycle, and may be stored for up to 30 days in accordance with the wrap manufacturer's instructions.

The MyoSure™ Instrument Tray has been validated for the following sterilization cycles:

Prevacuum Steam	**Gravity Steam**	**STERRAD 100S**
132°C (270°F)	132 °C (270 °F)	59% H_2O_2
4 minutes exposure	15 minutes exposure	Normal Cycle Setting
30 minutes dry time	30 minutes dry time	
Contents - 1 MyoSure Rod Lens Hysteroscope, 1 Removable Outflow Channel, 2 Seal Caps, 2 Light Guides	Contents - 1 MyoSure Rod Lens Hysteroscope, 1 Removable Outflow Channel, 2 Seal Caps, 2 Light Guides	Contents - 1 MyoSure Rod Lens Hysteroscope, 1 Removable Outflow Channel, 2 Seal Caps, 2 Light Guides

10.6 Comparison to Predicate

The design, principles of operation, primary functional specifications, and materials of composition of the MyoSure Instrument Tray are identical to those of the predicate PolyVac Surgical Instrument Delivery System. Both trays are made from the same materials, have the same dimensions, and are designed to be compatible with the same sterilization methods and parameters. Verification and Validation testing confirm that the MyoSure Instrument Tray meets the same performance specifications as the predicate PolyVac Surgical Instrument Delivery System.

10.7 Summary of Performance Testing:

Steam sterilization qualification:

The MyoSure Instrument Tray was successfully validated in the following steam sterilization cycles. Test results demonstrated a 6 log reduction of all spores strips and inoculated devices. Thermocouple data shows excellent sterilant penetration within the wrapped packages.

Validated Steam Sterilization Cycles:

Pre-Vacuum: 4 minutes @ 132C

Gravity Air Displacement: 15 minutes @ 132C

STERRAD Sterilization qualification

Successful completion of half cycle testing demonstrated that the MyoSure™ Instrument Tray containing a MyoSure Rod Lens Hysteroscope, Removable Outflow Channel, 2 Seal Caps, and 2 Light Guides components can be effectively sterilized using a the Sterrad® 100S System, full hospital cycle. The sterilization tests demonstrated a six log reduction capability of all spore strips and inoculated devices. Chemical indicator data indicated excellent sterilant penetration within the wrapped packages

Additional testing also included post-processing materials compatibility, intracutaneous irritation and hemolysis biocompatibility testing, all of which indicated successful results.

10.8 Conclusion

Based on the intended use, descriptive information, and performance evaluation provided in this submission, the MyoSure Instrument Tray has been shown to be substantially equivalent in materials, technology, method of operation, functional performance, and intended use to the predicate PolyVac Surgical Instrument Delivery System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 8, 2013

Mr. Daniel F. Phelan
Regulatory Affairs Manager
Hologic, Incorporated
250 Campus Drive
MARLBOROUGH MA 01752

Re: K121280
Trade/Device Name: MyoSure Instrument Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: January 17, 2013
Received: January 18, 2013

Dear Mr. Phelan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

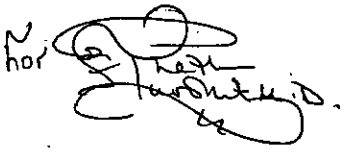
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K121280

Device Name: MyoSure Instrument Tray

Indications for Use:

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Contents - 1 MyoSure Rod Lens Hysteroscope and accessories	Contents - 1 MyoSure Rod Lens Hysteroscope and accessories	Contents - 1 MyoSure Rod Lens Hysteroscope and accessories)

Prescription Use____ or Over-the-counter use _X__
(per CFR 801.109)

Concurrence of CDRH

Elizabeth F. Claverie
2013.02.07 18:33:18 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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